

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 390326	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 04/18/2023
NAME OF PROVIDER OR SUPPLIER: ST. LUKE'S ANDERSON AMBULATORY SURGERY CENTER STATE LICENSE NUMBER: 24591501			STREET ADDRESS, CITY, STATE, ZIP CODE: 2200 ST. LUKE'S BLVD EASTON, PA 18045		
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S 0000	INITIAL COMMENT	S 0000			
S 033A	<p>This report is the result of a relicensure survey conducted onsite on April 18, 2023, at St. Luke's Anderson Ambulatory Surgery Center. It was determined that the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Ambulatory Care Facilities, Annex A, Title 28, Part IV, Subparts A and F, Chapters 551-573, November</p>	S 033A			
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE			TITLE: (X6) DATE:		

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S 033A	Continued from page 1 553.3 (1) Governing Body Responsibilities 553.3 Governing Body responsibilities include: (1) Conforming to all applicable Federal, State, and local laws. This REGULATION is not met as evidenced by:	S 033A	The Administrator, Director of Nursing and the Patient Safety Officer were educated that investigation reports and actions taken to promote patient safety must be submitted quarterly to the patient safety committee. The Patient Safety Officer will be responsible for providing investigation reports and the actions taken to promote patient safety quarterly at the patient safety committee meeting at Anderson ASC. The Administrator will be responsible for ensuring the investigation reports, including actions taken, are reflected in the patient safety committee meeting minutes quarterly. The Administrator is responsible for the plan of correction. Annually, the Administrator will be responsible for providing a report to the board regarding patient safety events and investigations at the Anderson Ambulatory Surgery Center.	Completion Date: 06/30/2023 Status: APPROVED Date: 05/30/2023	

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S 033A	<p>Continued from page 2</p> <p>Based on review of facility documents and staff interview (EMP), it was determined the facility failed to conform to applicable state laws.</p> <p>St. Luke's Anderson Ambulatory Surgery Center was not in compliance with the following State Law:</p> <p>Act 13 of 2002 Medical Care Availability and Reduction of Error (MCARE) Act, Chapter 3. Patient Safety Section 309. Patient safety officer. A patient safety officer of a medical facility shall do all of the following ... (4) Report to the patient safety committee regarding any action taken to promote patient safety as a result of investigations commenced pursuant to this section</p> <p>This is not met as evidenced by:</p> <p>Based on review of facility documents and staff interview (EMP), it was determined the patient safety officer failed to report to the patient safety</p>	S 033A			

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S 033A	<p>Continued from page 3</p> <p>committee actions taken to promote patient safety, as a result of the patient safety officer's investigations.</p> <p>Findings include: Review on April 18, 2023, of facility document "St, Luke's Patient Safety Plan, St. Luke's Anderson Ambulatory Surgery Center" reviewed December 2022, revealed "The Patient Safety Officer(s) shall do all of the following: 1. Serve on the Patient Safety Committee 2. Ensure the investigation of all reports of serious events and incidents 3. Take such action as is immediately necessary to ensure patient safety as a result of any investigation 4. Report to the Patient Safety Committee regarding any action taken to promote patient safety as a result of investigations commenced per items 1 through 3 above ..."</p> <p>Review on April 18, 2023, of the facility's "Patient Safety Committee" meeting minutes dated October 17, 2022, revealed "...Patient Safety Officer Report, Aggregate event data for July -Sept 2022, reviewed. Incident total: 14, Infrastructure Failures</p>	S 033A			

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S 033A	<p>Continued from page 4</p> <p>total: 3 reviewed ..." Continued review revealed no documentation the patient safety officer submitted investigation reports to the patient safety committee.</p> <p>Review on April 18, 2023, of the facility's "Patient Safety Committee" meeting minutes dated January 23, 2023, revealed "... Patient Safety Officer Report, Aggregate event data for July -Sept 2022, reviewed. Incident total:16, Infrastructure Failures total:0 reviewed, 2 Transfers this quarter ..."</p> <p>Continued review revealed no documentation the patient safety officer submitted investigation reports to the patient safety committee.</p> <p>Interview on April 18, 2023, with EMP2 at approximately 1:30 PM confirmed there was no documentation the patient safety officer submitted investigation reports to the patient safety committee.</p> <p>_____</p> <p>Based on review of facility documents and staff</p>	S 033A			

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S 033A	<p>Continued from page 5</p> <p>interview (EMP), it was determined the facility failed to conform to applicable state laws.</p> <p>St. Luke's Anderson Ambulatory Surgery Center was not in compliance with the following State Law:</p> <p>Act 13 of 2002 Medical Care Availability and Reduction of Error (MCARE) Act, Chapter 3. Patient Safety ... Section 309. Patient safety officer. A patient safety officer of a medical facility shall do all of the following ... (2) Ensure the investigation of all reports of serious events and incidents ... Section 310. Patient safety committee ... (b) Responsibilities. --A patient safety committee of a medical facility shall do all of the following: (1) Receive reports from the patient safety officer pursuant to section 309. (2) ..."</p> <p>This is not met as evidenced by:</p> <p>Based on review of facility documents and staff interview (EMP), it was determined the patient</p>	S 033A			

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S 033A	Continued from page 6 safety committee failed to receive reports from the patient safety officer to ensure the investigation of all reports. Findings include: Review on April 18, 2023, of facility document "St, Luke's Patient Safety Plan, St. Luke's Anderson Ambulatory Surgery Center" reviewed December 2022, revealed "... The Patient Safety Committee shall do all of the following: 1. Receive reports from the Patient Safety Officer(s) ... Evaluate investigations and action of the Patient Safety Officer(s) on all reports ..." Review on April 18, 2023, of the facility's "Patient Safety Committee" meeting minutes dated October 17, 2022, revealed there was a total of 17 safety events reported. Continued review revealed no documentation the committee reviewed patient safety investigation reports submitted by the patient safety officer.	S 033A			

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S 033A	Continued from page 7 Review on April 18, 2023, of the facility's "Patient Safety Committee" meeting minutes dated January 2023, revealed there was a total of 18 safety events reported. Continued review revealed no documentation the committee reviewed patient safety investigation reports submitted by the patient safety officer. Interview on April 18, 2023, with EMP2 at approximately 1:30 PM confirmed the meeting minutes provided no documentation the investigation of safety event reports was submitted for review by the patient safety committee.	S 033A			

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S 312Q		S 312Q			

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S 312Q	Continued from page 9 553.12 (b)(16) Implementation 553.12 (b) The following are the minimal provisions for the patient's bill of rights: (16) When an emergency occurs and a patient is transferred to another facility, the responsible person shall be notified. The institution to which the patient is to be transferred shall be notified prior to the patient's transfer. This REGULATION is not met as evidenced by:	S 312Q	The Medical Director of the ASC will be responsible to educate all providers that when an emergency occurs and a patient must be transferred to another facility, the receiving facility must be notified of the transfer. The Medical Director of the ASC will also educate all providers that they must document this notification in the patient's electronic medical record. The Administrator of the ASC will add to the "Transfer from ASU/PACU/OR to Hospital" policy that the facility is required to contact the receiving facility of an emergent transfer. The Director of Nursing or designee will be responsible for performing audits of electronic medical records of all transfers from the Anderson ASC to ensure there is documentation that the receiving facility was notified of the transfer. These audits will be reviewed with the Administrator of the ASC and will be reviewed at the quarterly Quality/PI committee meeting.	Completion Date: 06/30/2023 Status: APPROVED Date: 05/30/2023	

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S 312Q	Continued from page 10	S 312Q	The Administrator of the ASC will be responsible for the plan of correction and will review audit results at the quarterly Quality/PI committee meeting. Additionally, the Administrator will be responsible for providing a report to the board regarding annually regarding patient safety events and investigations at the Anderson Ambulatory Surgery Center.		

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S 312Q	<p>Continued from page 11</p> <p>Based on review of facility documents, medical records (MR), and interview with staff (EMP), it was determined the facility failed to notify the receiving facility that a patient was being emergently transferred in four of four medical records reviewed. (MR3, MR4, MR5 and MR6).</p> <p>Findings include:</p> <p>Review on April 18, 2023 of facility policy, "Transfer from ASU/PACU/OR to Hospital," last reviewed December 2022, revealed no documentation the facility was required to contact the receiving facility of an emergent transfer.</p> <p>Review of MR3 on April 18, 2023, revealed the patient in MR3 presented to surgery center on January 23, 2023, and experienced complications related to surgical procedure. Further review of MR3 revealed the patient required a transfer to higher level of care. Continued review revealed there was no documentation in MR3 the receiving</p>	S 312Q			

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S 312Q	Continued from page 12 facility was notified of an incoming patient transfer. Review of MR4 on April 18, 2023, revealed the patient in MR4 presented to surgery center on December 20, 2022, and experienced complications related to surgical procedure. Further review of MR4 revealed the patient required a transfer to higher level of care. Continued review revealed there was no documentation in MR4 the receiving facility was notified of an incoming Patient transfer. Review of MR5 on April 18, 2023, revealed the patient in MR5 presented to surgery center on April 4, 2023, and experienced complications related to surgical procedure. Further review of MR5 revealed the patient required a transfer to higher level of care. Continued review revealed there was no documentation in MR5 the receiving facility was notified of an incoming patient transfer. Review of MR6 on April 18, 2023, revealed the patient in MR6 presented to surgery center on April	S 312Q			

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S 312Q	Continued from page 13 4, 2023, and experienced complications related to surgical procedure. Further review of MR6 revealed patient required a transfer to higher level of care. Continued review revealed there was no documentation in MR6 receiving facility was notified of incoming patent transfer. Interview with EMP1 at approximately 12:30 PM on April 18, 2023, confirmed the above medical records did not contain documentation the receiving facility was notified of incoming emergent patient transfers.	S 312Q			
S 573A		S 573A			

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S 573A	Continued from page 14 557.3 (a) QA & Improvement Program 557.3 The Quality Assurance and Improvement Program (a) The quality assurance program shall include monitoring and evaluation of data collected, based on defined criteria that reflect current knowledge and clinical experience and relate to the care provided by the service. Sources of data include the medical records, incident reports, infection control records and patient complaints. The medial record shall contain sufficient data to support the diagnosis and determine that the procedures are appropriate to the diagnosis. Facilities that treat pediatric patients shall segregate data regarding such patients. This REGULATION is not met as evidenced by:	S 573A	The Administrator and Director of Nursing will be educated that pediatric quality data must be segregated from adult quality data which is reviewed at the ASC's Quality/PI committee meeting. Quarterly, the Administrator of the ASC will present quality data at the ASC's Quality/PI Committee meeting, separating pediatric data from adult data. This data will be included in the Quality/PI committee meeting minutes. The Administrator of the ASC will be responsible for the plan of correction. Annually, the Administrator will be responsible for providing a report to the board regarding quality data reviewed at the ASC's Quality/PI Committee meeting. This report will segregate pediatric quality data from adult quality data.	Completion Date: 06/30/2023 Status: APPROVED Date: 05/30/2023	

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S 573A	<p>Continued from page 15</p> <p>Based on a review of facility documents and employee interview (EMP) it was determined the facility failed to collect and segregate pediatric patient data for their quality assurance reports.</p> <p>Findings include:</p> <p>Review on April 18, 2023, of facility document "St. Lukes Anderson Ambulatory Surgery Center (SLAASC), Infection Control Plan, Calendar Year 2023," revealed "... The SLAASC is not for profit ambulatory surgery center located in the St. Luke's Specialty Pavilion (Anderson Campus). It serves the adult and pediatric patients ..."</p> <p>Review on April 18, 2023, of facility meeting minutes "PI Committee" dated July 18, 2022, October 17, 2022, and January 23, 2023, revealed the following quality measures were documented as reported during the meeting: Debrief/Time Out, TAT (turn around time), 1st Case Starts, Cancellation Rates, Pain audits. Further review revealed no</p>	S 573A			

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S 573A	Continued from page 16 documentation pediatric quality data was reported or segregated from the reported data. Interview on April 18, 2023, at approximately 9:15 AM with EMP2 confirmed pediatric data was not segregated in the facility's quality data collection and reporting.	S 573A			
S 574A		S 574A			

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S 574A	Continued from page 17 557.4 (a)(1-4) Quality Assurance & Improvement Committee 557.4 Quality Assurance & Improvement Committee (a) The committee shall consist of the following: (1) A practitioner who is not an owner, (2) A representative of administration, (3) A registered nurse, (4) Other health care personnel, as appropriate. This REGULATION is not met as evidenced by:	S 574A	The Coordinator of Accreditation and Standards will educate the Administrator of the ASC and the Director of Nursing that the Quality Plan must identify the required members of the Quality Improvement Committee. Annually, the Administrator of the ASC and Director of Nursing will review the list of members of the Quality Improvement Committee and update the list as needed. Annually, the Administrator of the ASC will review the Quality Plan and list of required members with the Coordinator of Accreditation & Standards to ensure accuracy. Additionally, the Administrator of the ASC will be responsible for providing a report to the board regarding the members of the Quality Improvement Committee of the Anderson Ambulatory Surgery Center on an annual basis.	Completion Date: 06/30/2023 Status: APPROVED Date: 05/31/2023	

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NAME OF PROVIDER OR SUPPLIER: ST. LUKE'S ANDERSON AMBULATORY SURGERY CENTER STATE LICENSE NUMBER: 24591501			STREET ADDRESS, CITY, STATE, ZIP CODE: 2200 ST. LUKE'S BLVD EASTON, PA 18045		
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S 574A	Continued from page 18 Based on review of facility documents and interview with staff (EMP) it was determined the facility's quality plan failed to identify the required members for the Quality Improvement Committee. Findings Include: Review on April 18, 2023, of facility document "Quality Management/Improvement and Data Collection PI (performance improvement) Process Plan," dated June 1, 2021, revealed no documentation for the required members of the committee. Interview on April 18, 2023, at approximately 9:30 AM with EMP2 confirmed the Quality Improvement Plan did not state the required members for the committee.	S 574A			
S 574C		S 574C			

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S 574C	Continued from page 19 557.4 (c)(1-3) Quality Assurance & Improvement Committee 557.4 Quality Assurance and Improvement Committee (c) Committee records of the activities shall include: (1) Reports made to the governing body, (2) Minutes of committee meetings including date, time, persons, attending, description and results of cases reviewed and recommendations made by the committee, (3) Corrective actions taken including appropriate orientation, and training or education programs necessary to correct deficiencies which are uncovered as a result of the quality assurance program. This REGULATION is not met as evidenced by:	S 574C	The Administrator and Director of Nursing will be educated that the Quality/PI committee meeting minutes must include the potential causes and problem resolution for any deficits identified in the quality measures that were reviewed. Quarterly, the Director of Nursing or designee will submit Quality meeting minutes including problem resolution for any deficits identified to the Administrator of the ASC. The Administrator of the ASC will be responsible for the plan of correction. Annually, the Administrator will be responsible for providing a report to the board regarding quality data measures and problem resolution for any deficits identified during the ASC's Quality/PI Committee meeting.	Completion Date: 06/30/2023 Status: APPROVED Date: 05/30/2023	

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S 574C	<p>Continued from page 20</p> <p>Based on review of facility documents and interview with staff (EMP), it was determined the quality improvement meeting minutes failed to document recommendations and corrective actions for quality measures reviewed for three of three meetings reviewed. (Q3 2022, Q4 2022 and Q1 2023)</p> <p>Findings include:</p> <p>Review on April 18, 2023, of facility document "Quality Management/Improvement and Data Collection PI (performance improvement) Process Plan", dated June 1, 2021, revealed "... Data is collected and analyzed from event reports, retrospective chart review, nursing audit and direct observation. If deficits are identified, potential causes and problem resolution are determined. Corrective action is required for compliance less than the identified measurable performance goal ... "</p> <p>Review on April 18, 2023, of the "PI Committee" meeting minutes for Q3 2022, Q4 2022 and Q1</p>	S 574C			

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S 574C	Continued from page 21 2023, revealed the following quality measures were documented as reviewed at the meeting and did not meet established compliance rates: TAT (turn around time), 1st Case Starts, Cancellation Rates, Pain audits. Further review revealed no documentation of potential causes and problem resolution. Interview on April 18, 2023, at approximately 9:30 AM with EMP2 confirmed recommendations and corrective actions were not documented in the meeting minutes for quality measures that did not meet compliance rates.	S 574C			
S 6747		S 6747			

Pennsylvania Department of Health

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S 6747	Continued from page 22 567.43 Ventilation System The ventilation system shall be inspected and maintained in accordance with the written maintenance schedule to ensure that a properly conditioned air supply meeting minimum filtration, humidity and temperature requirements is provided in critical areas such as the surgical and recovery suites under Chapter 571 (relating to construction standards). This REGULATION is not met as evidenced by:	S 6747	All of the monitoring of temperature and humidity at the Anderson ASC will be the responsibility of the engineering department around the clock, including weekends. The Engineering Department will be responsible for notifying the ASC when temperature and/or humidity has fallen out of range. The current "Monitoring of Temperature and Humidity" policy will be changed to reflect this process by the Administrator of the ASC. Quarterly, temperature and humidity data will be presented by the facility director to the Administrator and Infection Preventionist and reviewed at the ASC's Infection Control Committee meeting. The Administrator will be responsible for the plan of correction and will review temperature and humidity report data quarterly. Annually, the Administrator will be responsible for providing a report to the board regarding temperature and humidity data.	Completion Date: 06/30/2023 Status: APPROVED Date: 05/30/2023	

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S 6747	Continued from page 23 Based on review of facility documents and interview with facility staff (EMP), it was determined that the facility failed to ensure the ventilation system met the temperature requirements. Findings include: Review on April 18, 2023, of the facility policy "Monitoring of Temperature and Humidity in the Ambulatory Surgery Center" reviewed December 2022, revealed "To establish protocol for the daily monitoring and logging of temperature and humidity in the Operating Room/Procedure Rooms in an attempt to minimize the static electricity and reduce the potential for bacterial growth ... Relative humidity shall ordinarily be maintained between 30% and 60%. The temperature range in the Operating Room/Procedure Rooms will be maintained at a range of 68° to 73° F. Deviations from the acceptable range will be reported to the Engineering Department ... " 1. Review on April 18, 2023, of facility document	S 6747			

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S 6747	<p>Continued from page 24</p> <p>"St. Luke's Anderson ASP OR (operating room)/Humidity" record for March 2023, revealed OR1 room temperatures were recorded as below the required room temperatures on March 8 and 9 and OR4 room temperatures were recorded as below the required temperatures on the 1, 2, 3, 6, 7, 8, 9, 16, 17, 20, 21, 22, 23, and 24. Further review revealed no documentation temperatures were recorded for OR1, OR4, OR5, OR6 on March 4, 5, 11, 12, 18, 19, 25 and 26. Continued review revealed no documentation deviations were reported to the engineering department.</p> <p>2. Review on April 18, 2023, of facility document "St. Luke's Anderson ASP OR (operating room)/Humidity" record for April 2023, revealed OR1 room temperatures were recorded below the required room temperatures on April 7, 11 and 18; OR4 room temperatures were recorded as below the required temperature on April 5, 6, 7, 12, 13, 14, 17, and 18, and OR5 room temperatures were recorded below the required temperatures on April 7 and 18. Further review revealed no</p>	S 6747			

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S 6747	Continued from page 25 documentation temperatures were recorded for OR1, OR4, OR5, OR6 on April 1, 2, 8, 9, 15, and 16. Continued review revealed no documentation deviations were reported to the engineering department. 3.Review on April 18, 2023, of facility document "Temperature and Humidity Monitoring Record, SPD & Prep Pack, Temperature: 68° to 73°, Humidity 30% and 60%" revealed room temperatures for the sterile processing area and surgical instrument packing area were recorded as below the required temperatures on March 6, 9, 13, 14, 15, 16, 20, 21, and 29. Further review revealed no documentation temperatures were recorded on March 1, 2, 11, 12, 18, 19, 25 and 26. Continued review revealed no documentation the engineering department deviations were reported to the engineering department. 4.Review on April 18, 2023, of facility document "Temperature and Humidity Monitoring Record, SPD & Prep Pack, Temperature: 68° to 73°,	S 6747			

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S 6747	<p>Continued from page 26</p> <p>Humidity 30% and 60%" revealed no documentation room temperatures for the sterile processing area and surgical instrument packing area were recorded on March 1, 2, 11, 12, 18, 19, 25 and 26.</p> <p>5. Review on April 18, 2023, of facility document "Temperature and Humidity Monitoring Record, SPD Decontamination, Temperature: 60° to 73°, Humidity N/A" revealed no documentation room temperatures for the decontamination area were recorded on March 1, 2, 11, 12, 18, 19, 25, 26 and April 1, 2, 8, 9, 15, and 16.</p> <p>Interview on April 18, 2023, at approximately 11:30 AM, EMP2 confirmed the above temperature documentation and confirmed there was no documentation the engineering department was notified of deviations in the temperatures.</p>	S 6747			



Certified End Page

ST. LUKE'S ANDERSON AMBULATORY SURGERY CENTER

STATE LICENSE NUMBER: 24591501

SURVEY EXIT DATE: 04/18/2023

**I Certify This Document to be a True and Correct Statement of Deficiencies and
Approved Facility Plan of Correction for the Above-Identified Facility Survey**

A handwritten signature in black ink that reads "Jeane Parisi".

Jeane Parisi
Deputy Secretary for Quality Assurance

A handwritten signature in black ink that reads "Debra L. Bogen MD".

Debra L. Bogen, MD, FAAP
Acting Secretary of Health



THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY